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Food and Drug Administration
Nashville District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

297 Plus Park Boulevard
Nashville, TN 37217

July 24, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. Michael T. Hudson
President
Hudson Foods, Inc.
P. O. Box 777
Rogers, AR 72756

WARNING LETTER - 97-NSV-13

Dear Mr. Hudson:

An inspection of your medicated feed mill located on Railroad Avenue in Albertville, Alabama, by an investigator of the Food and Drug Administration from April 29 through May 6, 1997, found significant deviations from current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause feeds being manufactured at your facility to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection found incorrect formulation of feeds containing penicillin, incorrect labeling accompanying finisher feeds containing Roxarsone, failure to conduct all of the required assays of feeds containing Category II Type A Medicated Articles, and failure to conduct follow-up investigations of finished feed assay results that were out of specifications.

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture are in compliance with the law.

You should take prompt action to correct these CGMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanction. These

sanctions include, but are not limited to, seizure, injunction, and/or denial or revocation of your feed mill license as provided for at section 512m of the Act [21 U.S.C. 360b(m)].

This letter constitutes official notification under the law. Based on the results of the above noted inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

We acknowledge receipt of Mr. Rutledge's July 2, 1997, response to the list of inspectional observations issued to him at the termination of the subject inspection. That response addresses the matters of primary concern, but the adequacy of the stated changes and corrections can only be evaluated by reinspection at a future date. Any further correspondence regarding the inspection should be directed to Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,

Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosures:
[Surplus copy of Title 21, Code of Federal Regulations, Parts 200 to 299]

cc: Gerald Randolph
General Manager
Hudson Foods, Inc.
P. O. Box 1097
Albertville, AL 35950